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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,853	10/17/2007	Katsumi Aoyagi	053466-416	4864

22428 7590 10/11/2011
FOLEY AND LARDNER LLP
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER

HORNING, MICHELLE S

ART UNIT	PAPER NUMBER
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1648

MAIL DATE	DELIVERY MODE
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10/11/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/577,853	Applicant(s) AOYAGI ET AL.	
	Examiner MICHELLE S. HORNING	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1,2,4,5,7-14,16-21 and 24-29 is/are pending in the application.
- 5a) Of the above claim(s) 2,8-14,16-21 and 24-29 is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1, 4, 5, 7 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/26/2011</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1, 4, 5 and 7 are under current examination.

Any rejection(s) and/or objection(s) not reiterated herein have been withdrawn.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/7/2011 has been entered.

Information Disclosure Statement

The information disclosure statement filed 8/26/2011 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Specifically, the reference Cite No. F7 was not provided and this reference has been crossed out on the IDS.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Aoyagi (EP 0967484-cited by the IDS).

The claims are directed to (in part): a method of treating a sample suspected of containing HCV, which method comprises treating the sample with a treating agent containing: an acidifying agent and a cationic surfactant having both a straight chain alkyl group of 10 or more carbon atoms, and a tertiary amine or a quaternary ammonium salt in the same molecule, wherein the method effects the release of the HCV antigen and the inactivation of antibodies that bind to the HCV antigen; see instant claim 1.

Aoyagi teaches a method of treating a sample comprising HCV; see abstract and at least para. [0002]. The method comprises treating the sample with an acidifying agent, including hydrochloric acid, sulfuric acid, acetic acid, trichloroacetic acid and trifluoroacetic acid, in combination with a cationic surfactant having a straight chain alkyl group of 10 or more carbon atoms and a tertiary amine or a quaternary ammonium salt in the same molecule; see abstract, para. [0080] and [0091]. The reference discloses using dodecyltrimethylammonium as a surfactant; see para. [0091]. Aoyagi also teaches using a probe that binds to the viral antigen thereby determining if HCV is present; see para. [0028] and claim 4, step (2). Because Aoyagi describes the same step(s) using the same composition, the same results must occur as instantly claimed (*i.e.* the release of the HCV antigen and the inactivation of antibodies that bind to the HCV antigen). Also see MPEP 2112.01 II. COMPOSITION CLAIMS-IF THE

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COMPOSITION IS PHYSICALLY THE SAME, IT MUST HAVE THE SAME PROPERTIES.

Thus, Aoyagi anticipates the claimed method.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aoyagi (EP 0967484-cited by the IDS) in view of US Patent 6727092 (hereinafter as "Shah"-see attached form 892).

Claim 7 discloses using the cationic surfactant dodecyltrimethylammonium *bromide*.

While Aoyagi teaches using a dodecyltrimethylammonium (see para. [0091]), Aoyagi describes not explicitly teach using a dodecyltrimethylammonium *bromide*.

Shah teaches the use of a surfactant to remove the lipid envelope of HCV, thereby exposing the HCV core protein to solution; see col. 27, lines 55+. Shah specifically discloses using the surfactant, dodecyltrimethylammonium bromide, in compositions for detecting HCV antigen; see Table VIII, col. 30.

It would have been obvious to one of ordinary skill in the art to use the bromide salt form of dodecyltrimethylammonium in the method taught by Aoyagi. One would have been motivated to do so because dodecyltrimethylammonium bromide has been shown to be used in compositions for detecting HCV in a sample (the same field of endeavor).

There would have been a reasonable expectation of success given the underlying materials and methods are widely known and commonly used as evidenced by the prior art (*e.g.* use of surfactants, including dodecyltrimethylammonium bromide, in detecting HCV in a sample).

The invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments with respect to claims 1, 4, 5 and 7 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

No claim is allowed at this time.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELLE S. HORNING whose telephone number is (571)272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ZACHARIAH LUCAS can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MICHELLE S HORNING/
Examiner, Art Unit 1648